Transaortic transcatheter aortic valve implantation: experience from the Kiel study

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Abstract

OBJECTIVES: To evaluate the efficacy and safety of Edwards SAPIEN-XT or SAPIEN-3 transcatheter heart valves via transaortic (TAo) access.

METHODS: A total of 100 consecutive patients with severe symptomatic aortic stenosis undergoing TAo-transcatheter aortic valve implantation (TAVI) were included in this observational registry (November 2012–December 2014). Periprocedural and post-procedural outcomes were assessed.

RESULTS: Of these 100 patients, 1 received a Medtronic CoreValve. Therefore, this patient was subsequently removed from the analysis. Ninety-nine consecutive TAo-TAVI patients received a balloon-expandable transcatheter heart valve (Sapien). The SAPIEN-XT valve was implanted in 53 patients and the SAPIEN-3 valve in 46 patients. Mean fluoroscopy time was shorter in the SAPIEN-3 cases (8.1 ± 5.1 min, SAPIEN-XT; 8.1 ± 5.1 min, SAPIEN-3; P = 0.004), with fewer patients requiring dilatation after the operation (20.5% SAPIEN-3 vs 64.2% SAPIEN-XT; P < 0.0001). There were no other significant differences in procedural characteristics between the two valves. All-cause 30-day mortality was 5.1% overall, with comparable outcomes for the two valves (5.7 and 4.4% for SAPIEN-XT and SAPIEN-3 valves, respectively; OR, 1.32; 95% CI, 0.21–8.27; P = 1.0). New atrial fibrillation (13.1%) and acute kidney injury (11.1%) were the most common complications during the procedure. There were no other significant differences between the two valves. All-cause mortality at 1 year was 11.1%, with comparable outcomes for the two valves (10.2% SAPIEN-XT vs 12.2% SAPIEN-3; P = 0.81). There were no other significant differences between the two valves. All-cause mortality at 1 year was 11.1%, with comparable outcomes for the two valves (10.2% SAPIEN-XT vs 12.2% SAPIEN-3; P = 0.81). There were no other significant differences between the two valves. All-cause mortality at 1 year was 11.1%, with comparable outcomes for the two valves (10.2% SAPIEN-XT vs 12.2% SAPIEN-3; P = 0.81).

CONCLUSIONS: The efficacy and safety of the Edwards SAPIEN-XT or SAPIEN-3 heart valves via TAo access were demonstrated by high procedural success and low complication rates. The data indicate that this approach is a viable alternative to established access routes.

Keywords: Transcatheter heart valve • Transcatheter aortic valve implantation • Transaortic access • Aortic valve replacement • SAPIEN

INTRODUCTION

The prevalence of severe calcific aortic stenosis is rising as life expectancy increases and is progressively becoming a greater healthcare burden [1]. Although surgery is the standard of care in patients with acceptable surgical risk, transcatheter aortic valve implantation (TAVI) is a less invasive alternative for patients at high or prohibitive risk [2].

Typically, the femoral artery is used as the default access point; however, this route may bear a significant risk or be not feasible in a significant proportion of patients who have peripheral vascular disease or severe aortic calcification. Transapical access (TA) is the standard surgical approach for TAVI with very good results, but it is linked to a higher risk of bleeding complications and ventricular damage [3]. Furthermore, TA is not suitable for patients with respiratory disease or poor ventricular function or for frail patients [4, 5]. More recently, the use of transaortic (TAo) access has emerged, with preliminary results demonstrating good efficacy and safety [6, 7]. Bapat et al. [4] found similar 30-day mortality rates for TAo- and TA-TAVI and comparable complication rates in a small cohort of patients for whom a transfemoral (TF) procedure was not feasible. Similarly, Lardizabal et al. [8, 9] reported equivalent complication rates for these two procedures, whereas short- and long-term mortality rates were lower when TAo access was used.

The present study was carried out to evaluate the efficacy and safety of Edwards SAPIEN-XT or SAPIEN-3 transcatheter heart valves (THVs) inserted via the TAo approach and to assess its potential as an alternative access site.
MATERIALS AND METHODS

Study design

The present data are based on the experience of a single centre at the University Hospital Schleswig-Holstein (UKSH) in Kiel (Germany). All consecutive patients undergoing TAo-TAVI were enrolled from November 2012 to December 2014, irrespective of the valve to be deployed. All patients included in the registry provided written informed consent, and ethical approval was obtained from the institutional ethics board. The study was carried out in accordance with the Declaration of Helsinki.

Patients

Patients were included in this analysis if they were diagnosed with severe symptomatic calcific aortic stenosis and were at increased perioperative risk [elevated surgical risk scores such as the EuroSCORE I, EuroSCORE II and Society of Thoracic Surgeons (STS) score] as well-being at an advanced age (greater than 75 years) and/or another factor precluding conventional aortic valve replacement. The final decision to schedule the patients to undergo TAo-TAVI was made by the institutional interdisciplinary heart team. Patients were excluded from undergoing the TAo-TAVI procedure if they had a congenital unicuspid or bicuspid aortic valve, evidence of intracardiac mass, thrombus, vegetation, active infection or endocarditis, or if they were unable to tolerate anticoagulation/antiplatelet therapy. Furthermore, patients with excessive calcification of the anterior part of the ascending aorta (access site) were excluded. All patients were examined preoperatively according to a standardized TAVI protocol, including transoesophageal echocardiography (TOE), a cardiac CT scan and a CT scan of the complete aorta and the peripheral arteries.

Transcatheter heart valve and access route

Balloon-expandable THVs of the Edwards Sapien family have been used as standard valves in our centre. The self-expanding Medtronic CoreValve has been the first alternative THV. The decision as to the access route for the TAVI procedure (TF, TA or TAo) was made by the interdisciplinary heart team. The patient-adjusted decision was based on the patient’s comorbidities, frailty, results of the preoperative examinations and the patient’s preferences. Because it is our philosophy to provide the best therapeutic options for all patients, we meet the challenge of the TAVI procedures by offering alternative high-quality access routes.

Documentation

When a patient was admitted to the hospital, a full cardiac history was obtained, and any co-morbidities were recorded. Further data were collected at the time of the TAo-TAVI procedure, at discharge, at 30 days post-procedure (greater than or equal to 23 and less than 37 days) and at long-term follow-up. Complication rates were defined according to the Valve Academic Research Consortium (VARG)-2 criteria [10]. The information was entered into an electronic database.

Surgical procedure for transaortic-TAVI

All patients were operated on by the heart team in a hybrid operating room with direct access to a heart-lung machine and under general anaesthesia. A skin incision of 4 cm was made followed by a superior mini-J-sternotomy through the second right intercostal space in all TAo-TAVI patients. The pericardium was opened, and the access site of the ascending aorta was identified. Two 3–0 prolene purse string sutures reinforced with Teflon pledgets were placed at the ascending aorta after the administration of heparin (weight-adjusted) with an activated clotting time of at least 250 s. A diagnostic catheter was introduced through the femoral or radial artery in the non-coronary aortic sinus, and a pacing wire was placed through the femoral or jugular vein into the right ventricle. The aortic wall was punctured with a needle and a 6F 10-cm sheath was introduced. Typically, the aortic valve was crossed using a diagnostic 5F JR coronary catheter and a soft-tip straight standard wire. After the catheter was advanced into the left ventricle, the wire was exchanged for a manually preshaped 180 cm Amplatzer extra stiff wire placed in the apex of the left ventricle. In the next step, the 6F sheath was exchanged for the delivery sheath. For the SAPIEN-XT device, the Ascendra 2 system was used with a 22F sheath for 23- and 26-mm valves and a 26F sheath was used for a 29-mm valve; for the SAPIEN-3 device, the Certitude delivery system with an 18F (23- and 26-mm valve) or a 21F (29-mm valve) sheath was used. The Medtronic CoreValve Evolut R was utilized with the EnVeo R delivery system and a 18F Gore DrySeal sheath. Predilatation of the calcified aortic valve was performed in most cases. The valve was inserted and positioned in the aortic valve annulus. A stepwise deployment of the THV was performed under rapid pacing and fluoroscopy in a standardized manner. Finally, valve function, quantification of paravalvular leakage (PVL) and coronary status were determined by fluoroscopy with a contrast agent and TOE. After decannulation and haemostasis, pericardial drainage was introduced and the sternum was closed with three sternal wires.

Statistics

Descriptive statistics are provided for all evaluable data. Categorical variables are presented as absolute values and percentages. Continuous variables are given as means with corresponding standard deviations (SD). P-values were derived using the $\chi^2$, the Mann-Whitney–Wilcoxon and Fisher’s exact tests. For data analysis, SPSS Version 22 was used. P-values of <0.05 were considered statistically significant.

RESULTS

Patients

Overall, 332 patients were treated with a TAVI procedure at our institution from November 2012 to December 2014. Of these, 190 patients (57.2%) had a TF, 42 patients (12.7%) had a TA and 100 patients (30.1%) had a TAo access. All 100 consecutive TAo-TAVI patients were included in this study. Of these, 1 TAo-TAVI patient received a Medtronic CoreValve as a valve-in-valve procedure without any complications. Therefore, this patient was subsequently removed from the analysis. A total of 99 consecutive TAo patients received a balloon-expandable THV of the Sapien family. A SAPIEN-XT valve was used for 53 patients and a SAPIEN-3 valve for 46 patients (Fig. 1). Of the 99 patients receiving any of the balloon-expandable SAPIEN valves, the mean age was $81.9 \pm 5.7$ years and 67.7% were women (Table 1). Only 1 disabled patient in a wheelchair (1.0%) was New York Heart Association (NYHA) Class
I, with the majority being Class III (58.6%) or Class IV (21.2%). The total population had a wide variety of comorbidities, the most prevalent of which were coronary artery disease (63.6%), atrial fibrillation or flutter (AF; 47.5%), renal insufficiency (44.4%) and cerebrovascular disease (35.4%). Surgical risk according to the logistic EuroSCORE I criteria was 28.8 ± 15.4, whereas the surgical risk according to the logistic EuroSCORE II criteria was 8.7 ± 5.7, and that from the STS model was 7.6 ± 5.0. None of the recorded baseline characteristics displayed in Table 1 were significantly different in the SAPIEN-XT versus the SAPIEN-3 cohort.

**Procedural characteristics**

The 26-mm valves were the most frequently used for both the SAPIEN-XT (58.5%) and the SAPIEN-3 (63.0%; Table 2) patients. The larger 29-mm valve was used for 24.5% of SAPIEN-XT procedures, but just 4.3% of SAPIEN-3 procedures, with the smaller 23-mm valve used for 17.0% (SAPIEN-XT) and 32.6% (SAPIEN-3), respectively.

The mean incision-to-suture time for the total population was 88.7 ± 25.6 min, with no significant difference between the valve types (P = 0.315). For the SAPIEN-XT valve, the mean fluoroscopy time was longer than for the SAPIEN-3 (8.1 ± 5.1 vs 5.6 ± 2.5; P = 0.004). The majority of patients underwent preprocedure balloon dilatation (96.0%), whereas 44.3% required post-procedure dilatation, with significantly more of the patients who received the SAPIEN-XT needing this procedure (64.2 and 20.5% of SAPIEN-XT and SAPIEN-3 patients, respectively; P < 0.0001). The decision to perform post-procedure dilatation was based on the judgement of the implanting surgeon, with PVL or incomplete expansion of the valve taken into account.

Conversion to open heart surgery was necessary in two cases, both of which received the SAPIEN-XT valve. One patient suffered a Stanford A aortic dissection after successful implantation of the THV caused by decannulation of the delivery sheath, probably due to a very thin aortic wall without calcification. This patient immediately received a replacement of the ascending aorta in deep hypothermic circulatory arrest with the THV remaining in situ. The postoperative course was uneventful except for a longer stay in

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**Figure 1:** Patient flow. TAo-TAVI: transaortic transcatheter aortic valve implantation; THV: transcatheter heart valve.

**Table 1:** Characteristics of patients operated by the TAo-TAVI approach

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total n (%) or mean ± SD, N = 99</th>
<th>SAPIEN-XT n (%) or mean ± SD, N = 53</th>
<th>SAPIEN-3 n (%) or mean ± SD, N = 46</th>
<th>P-value XT versus 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>81.9 ± 5.7</td>
<td>82.0 ± 5.3</td>
<td>81.8 ± 6.2</td>
<td>0.880</td>
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<tr>
<td>Gender (% female)</td>
<td>67 (67.7)</td>
<td>33 (62.3)</td>
<td>34 (73.9)</td>
<td>0.282</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>63 (63.6)</td>
<td>30 (56.6)</td>
<td>33 (71.7)</td>
<td>0.145</td>
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<tr>
<td>Myocardial infarction</td>
<td>11 (11.1)</td>
<td>6 (11.3)</td>
<td>10 (19.0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>47 (47.5)</td>
<td>27 (50.9)</td>
<td>20 (43.5)</td>
<td>0.546</td>
</tr>
<tr>
<td>Right bundle branch block</td>
<td>3 (3.0)</td>
<td>2 (3.8)</td>
<td>1 (2.2)</td>
<td>1.0</td>
</tr>
<tr>
<td>Mitral insufficiency</td>
<td></td>
<td></td>
<td></td>
<td>0.394</td>
</tr>
<tr>
<td>None</td>
<td>2 (2.1)</td>
<td>2 (3.8)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td>76 (78.4)</td>
<td>40 (75.5)</td>
<td>36 (81.8)</td>
<td></td>
</tr>
<tr>
<td>Grade II</td>
<td>19 (19.6)</td>
<td>11 (20.8)</td>
<td>8 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>16 (16.2)</td>
<td>9 (17.0)</td>
<td>7 (15.2)</td>
<td>1.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>20 (20.2)</td>
<td>10 (18.9)</td>
<td>10 (21.7)</td>
<td>0.804</td>
</tr>
<tr>
<td>COPD</td>
<td>20 (20.2)</td>
<td>8 (15.1)</td>
<td>12 (26.1)</td>
<td>0.214</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>35 (35.4)</td>
<td>20 (37.7)</td>
<td>15 (32.6)</td>
<td>0.675</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>11 (11.1)</td>
<td>5 (9.4)</td>
<td>6 (13.0)</td>
<td>0.750</td>
</tr>
<tr>
<td>PTCA</td>
<td>28 (28.3)</td>
<td>15 (28.3)</td>
<td>13 (28.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>CABG</td>
<td>2 (2.0)</td>
<td>0</td>
<td>2 (4.3)</td>
<td>0.213</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>31 (31.3)</td>
<td>14 (26.4)</td>
<td>17 (37.0)</td>
<td>0.284</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>44 (44.4)</td>
<td>22 (41.5)</td>
<td>22 (47.8)</td>
<td>0.173</td>
</tr>
<tr>
<td>NYHA</td>
<td></td>
<td></td>
<td></td>
<td>0.023</td>
</tr>
<tr>
<td>Class I</td>
<td>1 (1.0)</td>
<td>0</td>
<td>1 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Class II</td>
<td>19 (19.2)</td>
<td>15 (28.3)</td>
<td>4 (8.7)</td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>58 (58.6)</td>
<td>31 (58.5)</td>
<td>27 (58.7)</td>
<td></td>
</tr>
<tr>
<td>Class IV</td>
<td>21 (21.2)</td>
<td>7 (13.2)</td>
<td>14 (30.4)</td>
<td></td>
</tr>
<tr>
<td>EuroSCORE I</td>
<td>28.8 ± 15.4</td>
<td>28.0 ± 15.4</td>
<td>29.6 ± 15.7</td>
<td>0.617</td>
</tr>
<tr>
<td>EuroSCORE II</td>
<td>8.7 ± 5.7</td>
<td>8.2 ± 6.1</td>
<td>9.0 ± 6.1</td>
<td>0.538</td>
</tr>
<tr>
<td>STS score</td>
<td>7.6 ± 5.0</td>
<td>7.2 ± 5.0</td>
<td>8.2 ± 5.0</td>
<td>0.265</td>
</tr>
</tbody>
</table>


*a*Information missing for 2 patients.
the intensive care unit. The second patient had a left ventricular perforation from the guide wire. After the procedure was converted to open heart surgery, the perforation was secured with sutures without the need for extracorporeal circulation. The postoperative course was uneventful.

Overall, extubation was carried out in the operating room for 53.6% of patients, with 35.1% being extubated on the same day as the procedure, and the rest (11.3%) being extubated the following day. A much higher proportion of the SAPIEN-3 group was extubated in the operating room in comparison with the SAPIEN-XT group (31.4 and 78.3% for the SAPIEN-XT and SAPIEN-3 groups, respectively; \(P < 0.001\)).

### Functional outcomes

Aortic valve area increased from 0.73 cm\(^2\) prior to the procedure to 1.72 cm\(^2\) post-procedure, with similar increases found for each valve size (Fig. 2). The ejection fraction did not change greatly from before the procedure to after, irrespective of the valve implanted. The proportions of patients within the different categories of ejection fractions also remained fairly constant, with over half having a value greater than or equal to 55% both before and after the procedure.

### Paravalvular leakage

No patients experienced severe PVL, with a moderate level found for 3.8% of the SAPIEN-XT group but for none of the SAPIEN-3 group (Fig. 3). The remainder of the patients in the SAPIEN-XT group suffered mild leakage or none/trace (52.8 and 43.4%, respectively). Of the patients who received the SAPIEN-3 valve, the majority experienced none/trace leakage (82.6%), with the rest exhibiting a mild level of regurgitation (17.4%). There was a highly significant difference in post-procedural aortic valve regurgitation that favoured the SAPIEN-3 valve (\(P < 0.001\)).

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**Table 2:** Procedural characteristics of the transaortic transcatheter aortic valve implantation procedure

<table>
<thead>
<tr>
<th></th>
<th>Total n (%) or mean ± SD, N = 99</th>
<th>SAPIEN-XT n (%) or mean ± SD, N = 53</th>
<th>SAPIEN-3 n (%) or mean ± SD, N = 46</th>
<th>P-value XT versus 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 mm</td>
<td>24 (24.2)</td>
<td>9 (17.0)</td>
<td>15 (32.6)</td>
<td>0.01</td>
</tr>
<tr>
<td>26 mm</td>
<td>60 (60.6)</td>
<td>31 (58.5)</td>
<td>29 (63.0)</td>
<td></td>
</tr>
<tr>
<td>29 mm</td>
<td>15 (15.2)</td>
<td>13 (24.5)</td>
<td>2 (4.3)</td>
<td></td>
</tr>
<tr>
<td>Incision to suture time (min)</td>
<td>88.7 ± 25.6</td>
<td>91.1 ± 32.3</td>
<td>86.1 ± 14.3</td>
<td>0.315</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>6.9 ± 4.2</td>
<td>8.1 ± 5.1</td>
<td>5.6 ± 2.5</td>
<td>0.004</td>
</tr>
<tr>
<td>Volume of contrast agent (ml)</td>
<td>79.1 ± 35.4</td>
<td>85.0 ± 43.9</td>
<td>72.4 ± 21.0</td>
<td>0.070</td>
</tr>
<tr>
<td>Preprocedure balloon dilation</td>
<td>95 (96.0)</td>
<td>53 (100.0)</td>
<td>42 (91.3)</td>
<td>0.043</td>
</tr>
<tr>
<td>Post-procedure balloon dilation*</td>
<td>43 (44.3)</td>
<td>34 (64.2)</td>
<td>9 (20.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Conversion to open heart surgery</td>
<td>2 (2.0)</td>
<td>2 (3.8)</td>
<td>0</td>
<td>0.497</td>
</tr>
<tr>
<td>Extubation*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In operating room</td>
<td>52 (53.6)</td>
<td>16 (31.4)</td>
<td>36 (78.3)</td>
<td></td>
</tr>
<tr>
<td>Day of procedure</td>
<td>34 (35.1)</td>
<td>27 (52.9)</td>
<td>7 (15.2)</td>
<td></td>
</tr>
<tr>
<td>1 day post-procedure</td>
<td>11 (11.3)</td>
<td>8 (15.7)</td>
<td>3 (6.5)</td>
<td></td>
</tr>
</tbody>
</table>

**TAO-TAVI:** transaortic-transcatheter aortic valve implantation.

*a Information missing for 2 patients.

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**Figure 2:** Aortic valve area pre- and post-procedure. Mean ± SD of the pre- and post-procedural aortic valve area for the total population and by valve size.

**Figure 3:** Paravalvular leakage at Day 7 post-procedure. Severity of paravalvular leakage post-procedure. \(P < 0.001\) for comparison between valve types.
Table 3: Thirty-day outcomes with the transaortic-transcatheter aortic valve implantation procedure

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Total n (%), N = 99</th>
<th>SAPIEN-XT n (%), N = 53</th>
<th>SAPIEN-3 n (%), N = 46</th>
<th>OR (95% CI) (univariate)</th>
<th>P-value XT versus 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>5 (5.1)</td>
<td>3 (5.7)</td>
<td>2 (4.4)</td>
<td>1.32 (0.21–8.27)</td>
<td>1.0</td>
</tr>
<tr>
<td>Cardiac mortality</td>
<td>2 (2.0)</td>
<td>1 (1.9)</td>
<td>1 (2.2)</td>
<td>0.87 (0.05–14.24)</td>
<td>1.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>5 (5.1)</td>
<td>1 (1.9)</td>
<td>4 (9.0)</td>
<td>0.20 (0.02–1.88)</td>
<td>0.18</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>3 (3.0)</td>
<td>3 (5.7)</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Acute kidney injury*</td>
<td>11 (11.1)</td>
<td>8 (15.1)</td>
<td>3 (6.5)</td>
<td>2.55 (0.63–10.24)</td>
<td>0.213</td>
</tr>
<tr>
<td>Major or life-threatening bleeding</td>
<td>6 (6.1)</td>
<td>4 (7.5)</td>
<td>2 (4.3)</td>
<td>1.74 (0.33–9.05)</td>
<td>0.274</td>
</tr>
<tr>
<td>Coronary obstruction</td>
<td>2 (2.0)</td>
<td>2 (3.8)</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>New atrial fibrillation</td>
<td>13 (13.1)</td>
<td>6 (11.3)</td>
<td>7 (15.2)</td>
<td>0.71 (0.22–2.29)</td>
<td>0.767</td>
</tr>
<tr>
<td>New left bundle branch block</td>
<td>5 (5.1)</td>
<td>4 (7.6)</td>
<td>1 (2.2)</td>
<td>3.67 (0.40–34.11)</td>
<td>0.369</td>
</tr>
<tr>
<td>Atrioventricular block</td>
<td>8 (8.1)</td>
<td>3 (5.7)</td>
<td>5 (10.9)</td>
<td>0.49 (0.11–2.18)</td>
<td>0.466</td>
</tr>
<tr>
<td>New pacemaker</td>
<td>6 (6.1)</td>
<td>2 (3.8)</td>
<td>4 (8.7)</td>
<td>0.41 (0.07–2.36)</td>
<td>0.412</td>
</tr>
<tr>
<td>Hospitalization for TAVI-related reason</td>
<td>3 (3.0)</td>
<td>3 (5.7)</td>
<td>0</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

TAo-TAVI: transcatheter-aortic valve implantation; n.a.: not applicable.
*According to AKIN criteria.

Thirty-day outcomes

All-cause 30-day mortality was 5.1% (5 of 99 patients), with no significant differences between the two device groups (5.7 and 4.4% for the SAPIEN-XT and SAPIEN-3, respectively; OR: 1.32; 95% CI: 0.21–8.27; P = 1.0; Table 3). Cardiac mortality was 2.0%, corresponding to 1 patient from each group. The most prevalent complications during the first 30 days after the procedure were new AF (13.1%), acute kidney injury (11.1%) and atrioventricular block (8.1%). Pacemaker implantation was required for 6.1% of patients, 2 in the SAPIEN-XT group (3.8%) and 4 in the SAPIEN-3 group (8.7%; P = 0.412). Major or life-threatening bleeding complications occurred at a rate of 6.1% (6 patients), with no differences between the two valve types used. One intraoperative major bleeding event was caused by previous perforation of the left ventricle with the guide wire. Re-thoracotomy was necessary in 4 patients. Three patients had to be re-operated because of diffuse bleeding. One patient was re-operated for pericardial tamponade after resuscitation of unknown cause 3 days after the TAVI procedure.

Comparison of the transapical and transaortic approaches for TAVI

All 100 consecutive TAo-TAVI patients were compared to all 42 consecutive TA-TAVI patients in terms of pre-, intra- and postoperative parameters (Table 4; Fig. 4). Significant differences were found in the following preoperative parameters: age (years, TA/TAo: 75.5 ± 5.1/81.7 ± 5.7; P = 0.01); gender (% female, TA/TAo: 38.1%/68.0%; P = 0.001); cerebrovascular disease (TA/TAo: 14.3%/36.0%; P = 0.007); coronary artery disease (TA/TAo: 95.2%/64.0%; P < 0.0001); and EuroSCORE II (TA/TAo: 11.7 ± 6.8/8.6 ± 6.0; P = 0.007) whereas all other preoperative parameters (COPD, P = 0.85; renal insufficiency, P = 0.74; AF, P = 0.33; NYHA classification, P = 0.91; EuroSCORE I, P = 0.28 and STS score P = 0.89) revealed no significant differences between the two groups investigated. Overall, only one self-expanding (CoreValve) THV was implanted (TAo group). The implantation rate was 59.5%/53.0% for the SAPIEN-XT and 40.5%/46.0% for the SAPIEN-3 (TA/TAo access; P = 0.65) balloon-expandable valves. Incision-to-suture time (min, TA/TAo: 84.9 ± 40.2/86.6 ± 29.9; P = 0.58), volume of contrast agent (ml, TA/TAo: 80.0 ± 28.3/81.4 ± 35.7; P = 0.68) and post-procedure balloon dilatation (TA/TAo: 35.7%/43.0%; P = 0.69) were not significantly different in the TA- and TAo-access groups. The 30-day mortality rate was 9.5% (4/42 patients) in the TA group and 5.0% (5/100 patients) in the TAo group with no significant differences (P = 0.31). Long-term mortality was similar in both groups (TA/TAo: 38.1%/38.0%; P = 0.99) (Table 4; Fig. 4).

DISCUSSION

The use of TAo-TAVI is a relatively recent development. Early evidence suggests that this approach has a number of benefits; however, data from large cohorts are still lacking. We present our experience in 99 consecutive TAo-TAVI patients using the balloon-expandable Edwards SAPIEN-XT and SAPIEN-3 devices. To the best of our knowledge, this study represents the largest series of consecutive TAo-TAVI cases so far. The TAo access for TAVI resulted in good functional outcomes with low complication rates and low 30-day mortality rates. Implantation of the more recently developed SAPIEN-3 THV provided advantages over the SAPIEN-XT, but both devices were found to be safe and effective.

Patient characteristics

As expected for a TAVI cohort, the patients enrolled in this study had a high mean age and multiple comorbidities, corresponding to their high risk for open heart valve-replacement surgery. The majority of patients were NYHA Class III or IV and the surgical risk scores were high, independent of the criteria used. There were no significant differences between the characteristics of the patients who received the SAPIEN-XT valve and those who had the SAPIEN-3 valve implanted.

On the basis of the results of the standard preoperative analysis using CT scans, patients with excessive calcification of the anterior part of the ascending aorta (access site) were excluded. Typical contraindications for the TF or TA approach were small diameter calcifications and aortic root diameter < 21 mm.
or excessive calcifications of the femoral artery (TF) and left-ventricular aneurysm or dilated thin left myocardium (TA).

Procedural characteristics

More 29-mm SAPIEN-XT valves were used in comparison with 29-mm SAPIEN-3 valves. This pattern is reflective of the need for oversizing the earlier generation of THVs, which is required for the prevention of paravalvular regurgitation. In contrast, the SAPIEN-3 valve has an outer skirt that improves sealing with the native annulus, thereby reducing the degree of oversizing required [11]. It is therefore possible to use smaller valves, which is advantageous for preventing annulus rupture during the expansion of the balloon.

The procedure time was not significantly different from those that have been reported for TF- and TA-TAVI [12]. Furthermore, the duration of fluoroscopy and volume of contrast agent used were comparable or slightly lower than for the other access routes. Preprocedure balloon dilatation was used in the majority of patients, independent of the valve used. In contrast, post-procedure dilatation was required in a significantly higher proportion of patients who received a SAPIEN-XT valve in comparison with those that received a SAPIEN-3 valve, which also could be attributable to the improved sealing characteristics of the latter THV. The increased incidence of

### Table 4: Comparison of the transapical and transaortic approaches for transcatheter aortic valve implantation

<table>
<thead>
<tr>
<th></th>
<th>TA-TAVI n (%) or mean ± SD, N = 42</th>
<th>TAO-TAVI n (%) or mean ± SD, N = 100</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>75.5 ± 5.1</td>
<td>81.7 ± 5.7</td>
<td>0.01</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>16 (38.1)</td>
<td>68 (68.0)</td>
<td>0.001</td>
</tr>
<tr>
<td>COPD</td>
<td>9 (21.4)</td>
<td>20 (20.0)</td>
<td>0.85</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>19 (45.2)</td>
<td>44 (44.0)</td>
<td>0.74</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>6 (14.3)</td>
<td>36 (36.0)</td>
<td>0.007</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>16 (38.1)</td>
<td>47 (47.0)</td>
<td>0.33</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>40 (95.2)</td>
<td>64 (64.0)</td>
<td>&lt;0.0001</td>
</tr>
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<td>NYHA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>1 (2.4)</td>
<td>1 (1.0)</td>
<td>0.91</td>
</tr>
<tr>
<td>Class II</td>
<td>9 (21.4)</td>
<td>19 (19.0)</td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>23 (54.8)</td>
<td>58 (58.0)</td>
<td></td>
</tr>
<tr>
<td>Class IV</td>
<td>9 (21.4)</td>
<td>22 (22.0)</td>
<td></td>
</tr>
<tr>
<td>EuroSCORE I</td>
<td>31.6 ± 15.3</td>
<td>28.9 ± 15.4</td>
<td>0.28</td>
</tr>
<tr>
<td>EuroSCORE II</td>
<td>11.7 ± 6.8</td>
<td>8.6 ± 6.0</td>
<td>0.007</td>
</tr>
<tr>
<td>STS score</td>
<td>7.9 ± 5.5</td>
<td>7.7 ± 5.0</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>Intraoperative</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CoreValve</td>
<td>0</td>
<td>1 (1.0)</td>
<td>n.a.</td>
</tr>
<tr>
<td>SAPIEN THV</td>
<td>25 (59.5)</td>
<td>53 (53.0)</td>
<td>0.65</td>
</tr>
<tr>
<td>SAPIEN-XT</td>
<td>17 (40.5)</td>
<td>46 (46.0)</td>
<td></td>
</tr>
<tr>
<td>Incision to suture time (min)</td>
<td>84.9 ± 40.2</td>
<td>86.6 ± 25.9</td>
<td>0.58</td>
</tr>
<tr>
<td>Volume of contrast agent (ml)</td>
<td>80.0 ± 28.3</td>
<td>81.4 ± 35.7</td>
<td>0.68</td>
</tr>
<tr>
<td>Post-procedure balloon dilatation</td>
<td>15 (35.7)</td>
<td>43 (43.0)</td>
<td>0.69</td>
</tr>
<tr>
<td>Conversion to open heart surgery</td>
<td>0 (0.0)</td>
<td>2 (2.0)</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day mortality</td>
<td>4 (9.5)</td>
<td>5 (5.0)</td>
<td>0.31</td>
</tr>
<tr>
<td>Long-term mortality</td>
<td>16 (38.1)</td>
<td>38 (38.0)</td>
<td>0.99</td>
</tr>
</tbody>
</table>


Figure 4: Kaplan–Meier estimate for transapical (TA)- and transaortic (TAo)-TAVI patients. TAVI: transcatheter aortic valve implantation; N at risk: number at risk; months: months after TAVI procedure. P = 0.99 for comparison between TA- and TAO-TAVI.
acute kidney injury was probably mainly due to the more frequent redilatations and thus to the higher exposure to contrast medium in patients receiving a SAPIEN-XT valve (Tables 1 and 2). Emergency conversion to surgery was required in 2 patients, both of whom received a SAPIEN-XT valve.

Over half of the patients were extubated before leaving the operating room, with most of the others extubated the same day. This finding highlights the minimally invasive character of the TA access for TAVI procedures.

Major or life-threatening bleeding complications occurred at a rate of 6.1% with a need for rethoracotomy in 4 patients (4%). These findings are similar to those encountered with TA-TAVI procedures [12]. Sari et al. [13] reported a VARC bleeding complication rate of 11.7% in TF-TAVI patients using SAPIEN THV.

Seven-day outcomes

Transcatheter echocardiography at 7 days post-procedure showed that the mean aortic valve area was significantly larger after the TAVI, confirming efficacy of the procedure. Similar magnitudes of improvement were reported by Thourani et al. for both TA- and TAo-TAVI and by Leon et al. for TF-TAVI [14, 15]. On the other hand, there were no changes in the percentages of patients in the different ejection fraction categories, which is in agreement with other TAVI studies [16]. Improvements in ejection fraction will probably be more obvious after 3–6 months post-implantation than after 1 week.

Few patients experienced moderate PVL, and none experienced severe leakage. The majority of patients in the SAPIEN-3 group experienced either trace leakage or none at all. In contrast, over half of the patients in the SAPIEN-XT group displayed mild leakage. This finding is likely due to the improved sealing of the SAPIEN-3 valve with the native annulus, due to the presence of the outer skirt. Similar findings were reported by Amat-Santos et al. [17], although they noted a higher proportion of SAPIEN-3 patients who experienced mild leakage than was found in the present study (41 and 17.4%, respectively). This outcome may be attributed to the subjective nature of leakage assessment versus core laboratory adjudication.

Thirty-day outcomes

All-cause mortality at 30 days post-procedure was 5.1% (5 patients) in patients with a logistic EuroSCORE I of 28.8 ± 15.4, which is comparable to the rates of 6.8 and 7.4% previously reported for TAo-TAVI [16]. Studies of TA-TAVI have documented 30-day mortality rates between 4.0 and 18.2% [12, 18-21]. These higher values may be attributed to the greater risk of severe bleeding complications associated with the more invasive TA access route [3]. In the present study, cardiac mortality was found to be low at 2.0%, which is the same as that reported by Lardizabal et al. [9], but significantly lower than the 12.0% documented for TA-TAVI by the same authors.

The most common complication during the first 30 days post-procedure was the onset of AF. The noted rate of 13.1% is similar to that of 14.0% reported by Lardizabal et al. [9] but significantly lower than the 33.3% noted for TAVI-TAVI by Tanawuttiwat et al. [22]. However, it should be noted that the mean STS score for the patients in the latter study was much higher. The same authors reported that 52.8% of patients who underwent TA-TAVI developed AF, whereas 38.0 and 20.0% have been documented for a population of TA-TAVI patients with a mean STS score similar to that in our study [9, 23]. These data demonstrate the significantly lower risk of developing AF when the TAo access is used rather than the TA. The other most prevalent complications were kidney injury and atrioventricular block, with rates of other events found to be low, in agreement with other studies regarding TAo-TAVI [9]. Interestingly, the low rate of new pacemaker implantation of 6.1% (6 patients) following the TAo-TAVI procedures with balloon-expandable valves is remarkable. Hayashida et al. [16] reported pacemaker implantation for a similar proportion of patients receiving a THV via TAo access, although in that study, some patients had a self-expandable Medtronic CoreValve implanted. Nevertheless, the number of new pacemaker implantations remains low. We will analyse the rate of new pacemaker implantation again after 200 TAo-TAVI procedures and also compare our single-centre data to the results from the ROUTE registry to see if the TAVI approach has an influence on that issue [24].

Transaortic access route

Minimally invasive access routes in cardiac surgery are standardized approaches, e.g. for conventional aortic valve replacements via partial sternotomy. Also, the cannulation of the ascending aorta for extracorporeal circulation is a routine procedure for every cardiac surgeon. These conditions lead to a comfortable surgical situation for transaortic TAVI via superior mini-j-sternotomy. Additional advantages with TAo-TAVI are the ‘non-touch’ aortic arch technique, the closed pleura and the fast recovery of the patients due to reduced postoperative pain when sternotomy is used. When we used the partial sternotomy approach, we were able to reach every region of interest of the ascending aorta for the TAo-TAVI procedure, even in the off-midline ascending aorta. Another surgical approach for TAo-TAVI is parasternal access through the right second intercostal space, which includes opening the right pleura and, in several cases, ligation of the right internal thoracic artery [7]. We have no experience with that access site. With the presented series of patients, the TAo approach via a superior mini-j-sternotomy has become a well-established, innovative low-risk surgical access for TAVI at our centre. We plan to continue to use this technique in significant numbers in our interdisciplinary TAVI programme.

Comparison of transapical and transaortic access for TAVI

All 100 consecutive TAo-TAVI patients were compared to all 42 consecutive TA-TAVI patients operated in the same period of time concerning pre-, intra- and postoperative parameters (Table 4; Fig. 4). Data from the 42 TA-TAVI patients were analysed retrospectively and compared with data from the TAo group. Significant differences were shown only in preoperative parameters: age (TAo-TAVI patients were older; P = 0.01); gender (more female TAo-TAVI patients; P = 0.001); cerebrovascular disease (less in TA-TAVI patients; P = 0.007); coronary artery disease (more frequently occurring in TA-TAVI patients; P < 0.0001) and EuroSCORE II (higher score in TA-TAVI patients; P = 0.007), whereas all other preoperative parameters (COPD, renal insufficiency, AF, NYHA classification, EuroSCORE I and STS score) showed no significant differences between the two groups investigated. In particular, there were no
significant differences in the intra- and postoperative findings from the TA and TAO groups. Long-term mortality rates were similar for both TA-TAVI and TAO-Tavi, as demonstrated by the Kaplan–Meier estimate curve (Fig. 4).

We are currently performing a prospective study to compare the TAO and the TA approaches for TAVI with a focus on ventilation, extubation, recovery time, length of stays in the intensive care unit and the hospital. In cases where both the TA and the TAO approaches are feasible, we discuss the access route with the patient and with the interdisciplinary heart team. On the basis of our good experiences with the TAO access approach and the comfortable surgical situation with the routine partial sternotomy and aortic access approaches, we currently prefer the TAO approach to the TA approach.

The efficacy and safety of using the TAO access for TAVI have been demonstrated by the high procedural success and low complication rates. The data indicate that this approach is a viable alternative access route for TAVI patients.

Limitations

The main limitations to the present study were the relatively small number of patients who were included and the single-centre design; however, to the best of our knowledge, this collectively represents the largest series of consecutive TAO-TAVI cases published so far.

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Conflict of interest: none declared.

REFERENCES